DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TAIDOC TECHNOLOGY CORPORATION
PAUL LIU
REGULATORY AFFAIRS SPECIALIST
B1-7F, NO.127, WUGONG 2ND RD., WUGU DISTRICT
NEW TAIPEI CITY 24888 TAIWAN

May 7, 2015

Re: K143467
Trade/Device Name: FORA GD43 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: March 31, 2015
Received: April 2, 2015

Dear Mr. Paul Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143467

Device Name

FORA GD43 Blood Glucose Monitoring System

Indications for Use *(Describe)*

The FORA GD43 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by a single person and should not be shared. Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly).

The FORA GD43 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

The FORA GD43 Test Strips are for use with the FORA GD43 Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: k143467

1. Submitter Information

Company Name: TaiDoc Technology Corporation
Contact Person: Paul Liu
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Prepared Date: May 4th, 2015

2. Device name:

Proprietary Name: FORA GD43 Blood Glucose Monitoring System
Common Name: Blood Glucose Monitoring System
Product Code: NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase
Classification Panel: Clinical chemistry
Classification: Class II
Regulation Citation: 21 CFR §862.1345, Glucose test system

3. Predicate Device

Proprietary Name: FORA GD40 Blood Glucose Monitoring System
Common Name: Blood Glucose Monitoring System
510(k) Number: k101509

4. Intended Use

The FORA GD43 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by a single person and should not be shared. Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly).

The FORA GD43 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

The FORA GD43 Test Strips are for use with the FORA GD43 Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm).

5. Device Description:

The system consists of blood glucose meter and test strips. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only FORA GD43 test strips with the FORA GD43 Blood Glucose Monitoring System.

6. Comparison to the Predicate:

The modified FORA GD43 Blood Glucose Monitoring System has the following similarities to the predicate device:

- Same operating principle.
- Same functions and physical appearance.
- Same fundamental scientific technology.
- Same user interface.

The modifications:

- The material of test strip electrode is changed
- The sample volume required is changed

7. Test Principle:

The blood glucose is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter utilizes the current signal to calculate the blood glucose level.

8. Performance Characteristics:

Clinical and non-clinical studies were conducted to tested, verified and validated with respect to the predicate device to establish the performance of the FORA GD43 Blood Glucose Monitoring System. More than 95% of the individual glucose results fall within 15 mg/dL at glucose concentrations < 75 mg/dL and within ± 15 % at glucose concentrations ≧ 75 mg/dL. The CV (%) is less than 5% both in intermediate precision and repeatability. The data demonstrates that the FORA GD43 Blood Glucose Monitoring System is substantially equivalent to the predicate device.

9. Traceability:

FORA GD43 Blood Glucose Monitoring System is compared to the YSI 2300 Glucose Analyzer in the clinical and non-clinical studies. The YSI is calibrated with NIST (SRM) 917A reference material.

10. Conclusion:

Based on the information provided in this submission, the FORA GD43 Blood Glucose Monitoring System is substantially equivalent to the predicate FORA GD40 Blood Glucose Monitoring System.